



# UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 09/600,648   | 10/17/2000  | Shalaby Wahba Shalaby | 00537-165002        | 9033             |
| 37903  | 7590        | 04/07/2004            | EXAMINER            |                  |
| DAWN JANELLE AT<br>BIOMEASURE INC.<br>27 MAPLE STREET<br>MILFORD, MA 01757 |             |                       | NAFF, DAVID M       |                  |
|  |             |                       | ART UNIT            | PAPER NUMBER     |
|  |             |                       | 1651                |                  |

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/600,648

Applicant(s)

SHALABY, SHALABY WAHBA

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/30/03</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1651

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for  
5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/30/03 has been entered.

10 Claims examined on the merits are 1-46, which are all claims in the application.

The claims have not been amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

15 Claims 1-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recital of "bound microparticle" in line 1 of claim 1 and  
20 where recited in other claims is uncertain as to meaning and scope. It is uncertain how "bound" defines the microparticle. It is unclear as to whether "bound" is requiring the microparticle to bind a material or is requiring a material to bind the microparticle, or is requiring something else. Additionally, if "bound" is requiring  
25 binding between the microparticle and a material, it is uncertain as

Art Unit: 1651

to the material intended. If "bound" cannot be given a definite and clear meaning in relation to the microparticle, it should be canceled.

In line 3 of claims 23 and 25 and where recited in any other claims, "optionally" makes the metes and bounds of the claims unclear.

5 If the carrier is optional and not required, it should be canceled from the claims and required only when intended to be part of the composition.

In line 2 of claims 42 and 46, "a" should be replaced with --- the --- to be clear that the bound microparticle is that previously  
10 required in claim 12.

***Claim Rejections - 35 USC § 103***

Claims 1-11, 22, 23 and 26-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby et al (5,672,659) or Ignatious et al (WO 97/39738) in view of Shalaby (5,612,052) and Chesterfield et al  
15 (5,366,756).

The claims are drawn to a bound microparticle comprising an absorbable heterochain polymer core and one or more peptides and/or proteins immobilized on the core.

Shalaby et al ('659) and Ignatious et al disclose a composition  
20 containing a carboxyl group-containing polymer that can be a heterochain polymer conjugated with an amino group-containing bioactive polypeptide or a drug that is a polypeptide. The conjugate may be formed into microparticles. The conjugate is formed by combining a solution of the polymer with a solution of the

Art Unit: 1651

polypeptide. See cols 2 and 3 of Shalaby et al and pages 4-9 of Ignatious et al.

Shalaby et al ('052) discloses coating microparticles with a drug to provide controlled release of the drug (col 7, lines 30-33).

5 Chesterfield et al disclose polymer particles coated with a tissue growth promoter and if desired a therapeutic agent for implanting to repair tissue (cols 1-3).

The present invention differ from Shalaby et al ('659) and Ignatious et al in that in the claims the polymer is formed into a  
10 microparticle and the polypeptide or protein is immobilized on the microparticle, whereas Shalaby et al and Ignatious et al form the conjugate by combining solutions of the polymer and polypeptide or protein and form a microparticle of the conjugate.

It would have been obvious to form the polymer of Shalaby et al  
15 ('659) or Ignatious et al into a microparticle prior to conjugating with the polypeptide or protein as suggested by Shalaby et al ('052) and Chesterfield et al forming a polymer microparticle and immobilizing a drug and/or growth promoter on the microparticle. Forming the microparticle before binding the protein or polypeptide  
20 would have been expected to provide the protein or polypeptide on the surface of the microparticle and make it more readily available. The conditions of dependent claims would have been matters of obvious choice in view of conditions disclosed by the references.

Art Unit: 1651

***Claim Rejections - 35 USC § 103***

Claims 12-21, 24, 25 and 34-46 are rejected under 35  
U.S.C. 103(a) as being unpatentable over the references as applied to  
claims 1-11, 22, 23 and 26-33 above, and further in view of Auer et al  
5 (WO 92/11844) and Demian et al (5,795,922).

The claims require the bound microparticle containing the  
immobilized protein or polypeptide to be encased.

Auer et al disclose forming a complex of a protein pharmaceutical  
agent and a polycationic reagent, and encapsulating the complex in a  
10 microsphere (pages 4-9) to provide sustained release of the protein.

Demian et al disclose microencapsulating radiopacifier particles  
to prevent agglomerating (col 3).

When modifying Shalaby et al ('659) or Ignatious et al by forming  
the polymer into a microparticle before binding the protein or  
15 polypeptide as set form above, it would have been obvious to  
encapsulate the protein or polypeptide-containing microparticle as  
suggested Auer et al to provide sustained release and as suggested by  
Demian et al to prevent agglomerating.

***Conclusion***

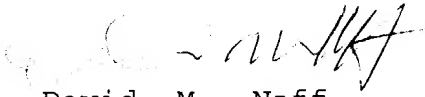
20 Any inquiry concerning this communication or earlier  
communications from the examiner should be directed to David M. Naff  
whose telephone number is 571-272-0920. The examiner can normally be  
reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,  
25 the examiner's supervisor, Mike Wityshyn can be reached on 571-272-

Art Unit: 1651

0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
15 4/5/04